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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/051,443	04/10/1998	CARIN WIDERSTROM	06275/124001	8003

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EXAMINER
WEISS JR, JOSEPH FRANCIS

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/051,443	Widerstrom
Examiner	**Art Unit**
Joseph Weiss	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 15, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5 and 7-12* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-5 and 7-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-5 & 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goettenauer et al (DE 4400084 A1) in view of Gonda (US 5743250).

In regards to claim 1, Goettenauer discloses an inhaler (33) comprising an inhalation channel (21); a first container (1) for containing medicament; a first release means (3/28) to release medicament into the channel; a subsidiary container (1) for containing medicament; a subsidiary release means (3/28) to release the subsidiary container's medicament into the inhalation channel; wherein the two release means are independently operable which results in one or more of each containers being operated to release medicament into the channel at the same time to vary dosage and which is fully capable of having different fractions or relative ratios of medicament contained within the different medicament containers to include where the subsidiary container which may contain a dose that is a predetermined fraction that is less than that of the first dose, but does not explicitly disclose such. However, Gonda disclose such (note the abstract which discloses repeated deliveries of medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these

differences being predetermined when the blisters are filled, note the abstract for the use of a dry powder). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Goettenauer. The suggestion/motivation for doing so would have been to provide for a more customized dosing regime that would compensate for the losses of medicament that accompany inspiratory delivery, col. 4 lines 25-30. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 2, Goettenauer discloses the containers as being integral with the inhaler.

In regards to claim 3, Goettenauer discloses the containers as being depressions in at least one wall of the inhalation channel with the release means comprising films that seal the depressions.

In regards to claim 5, Gottenauer & Gonda disclose the medicament used as being in a powdered form.

In regards to claim 7, Gottenauer discloses the inhaler as having at least 2 subsidiary containers which are fully capable of containing at least 2 subsidiary doses which are a predetermined fraction of a first dose in a first container which may contain a dose that is a predetermined fraction that is less than that of the first dose.

In regards to claim 8, the suggested device discloses subsidiary doses with different fractions of a first dose which may contain a dose that can be a predetermined fraction that is less than that of the first dose. (See Gonda Col. 42 lines 6-50 & note the operation of Gonda regarding partial blister contents delivery).

In regards to claim 4, the suggested device discloses the release means as comprising one or more elongated members (See Goettenauer Fig 8) attached to or integral with said films (by dint of container film 36 which is integral with cover film 3) and with free ends which may be pushed by a user in order to remove the films from their respective depressions, thereby releasing medicament contained within the respective depressions, but applicant arranges its release means to a user my pull instead of push, i.e. a reversal of known parts for a known purpose.

It is noted that applicant's specification does not set forth this reversal of parts, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of

mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

3. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottenauer et al (5881719) in view of Gonda (US 5743250).

In regards to claim 9, Gottenauer discloses the a method of providing a variable dose in a single inhaler that provides an inhalation channel (7) through which a user may inhale. A first container (31) for containing a first dose (38) and a first release means (9) for releasing a first dose said method further comprising providing at least one subsidiary container (any of the other blisters 31), containing a subsidiary dose (the dose withing any of the other containers 31) which provides an independently operable subsidiary release means (any other of levers 9) arrangement for releasing the subsidiary dose into the inhalation channel such that one or both of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose may be provided, but does not explicitly disclose the subsidiary dose being a predetermined fraction that is different from the first dose. However, Gonda disclose the use of predetermined fractions of doses of one blister relative to another for use in medicament delivery devices wherein some of the doses are a lesser fraction of medicament relative to a greater dose contained in another blister and via the blood glucose monitoring permits the user to determine if the need exists to repeat the dosing and/or include subsidiary doses. (note the abstract which discloses repeated deliveries of medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these

differences being predetermined when the blisters are filled, note the abstract for the use of a dry powder). The references are analogous since they are from the same field of endeavor, the medicament delivery arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Gottenauer. The suggestion/motivation for doing so would have been to more accurately tailor the amount of drug delivered to a user for modulating the physiological parameter appropriately. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 10, Gottenauer discloses the a method of providing a variable quantity of a substance in a channel for an administration device comprising the steps of opening a first container (31) containing a first dose (38) of a substance and dispensing the substance in the channel and selectively opening a subsidiary container (any of the other blisters 31), containing a subsidiary dose (the dose within any of the other containers 31) and representing a total quantity of substance required and dispensing the substance in into the channel, but does not explicitly disclose the subsidiary dose being a predetermined fraction that is different from the first dose which is less than the first dose. However, Gonda disclose the use of predetermined fractions of doses of one blister relative to another for use in solid medicament delivery devices wherein some of the doses are a lesser fraction of medicament relative to a greater dose contained in another blister. The references are analogous since they are from the same field of endeavor, the medicament delivery arts. At the time the instant application's invention was made, it would have

been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Gottenauer. The suggestion/motivation for doing so would have been to more accurately tailor the amount of drug delivered to a user for modulating the physiological parameter appropriately. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 11, the suggested device discloses that the substance is medicament.

In regards to claim 12, the suggested device discloses the administration device as an inhaler.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-5 & 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting (Common Assignee) as being unpatentable over claims 1-19 of U.S. Patent No. 5533505 in view of Gonda. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set forth an inhaler having an inhalation channel

with a container formed a depression in a wall of the inhaler that is integral with the container for containing a dose of medicament with a film release means that is pulled by a user for the release of medicament, however the claims of the instant application set forth the use of multiple containers, whereas US 5533505 discloses the use of only one such container, i.e. the duplication of a known part for a known purpose, but Gonda discloses such. (note the abstract which discloses repeated deliveries of medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these differences being predetermined when the blisters are filled, note the abstract for the use of a dry powder). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Goettenauer. The suggestion/motivation for doing so would have been to provide for a more customized dosing regime that would compensate for the losses of medicament that accompany inspiratory delivery, col. 4 lines 25-30. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, it is noted that applicant's specification does not set forth the duplication of a known part for known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, **barring a convincing showing of evidence to the**

contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather that to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Response to Arguments

6. Applicant's arguments filed 15 Oct 02 have been fully considered but they are not persuasive.

In general please note:

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

For further elaboration beyond the reasoned basis of the rejection regarding the claim term "Subsidiary" dose please note the following:

1-The written description provides no unique definition of scope regarding the claim term "Subsidiary"

2-The term "Subsidiary" has no art unique definition or scope

3-Therefore the term "Subsidiary" is given its plain language meaning.

4-Applicant's use of the term is that of an adjective, i.e. describing what the dose is.

5-The plain meaning of "Subsidiary" as an adjective is as follows:

--Furnishing aid or support (Auxillary); of secondary importance; Webster's Collegiate Dictionary 12th ed. Page 1174; See also Roget's Thesaurus Expanded Edition.

--Hence the plain language meaning of the claim term "Subsidary dose" is that of a dose that is secondary or auxillary to another dose. Logically, from this any device that provides for the presence of multiple doses and has the capability of having more than one dose released for delivery at the same discrete point in time provides "Subsidiary" doses.

Regarding the provision of a "variable" dose, by sheer force of logic by providing a subsidiary dose the first dose then dose is varied, hence the intended result of a "variable" dose is achieve.

Thus all of applicant's arguments for the basis of rejection not being proper are in error, and the rejection is retained.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, can be reached at telephone number (703) 308-2702. The official fax number for this group is (703) 305-3590 or x3591.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

JFweiss

December 10, 2002

Aaron J. Lewis
Primary Examiner